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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/659,413	09/10/2003	Peter Kite	13317.1001cip	4621

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EXAMINER	
KANTAMNENI, SHOBHA	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 02/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/659,413	KITE ET AL.	
	Examiner	Art Unit	
	Shobha Kantamneni	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 December 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *32,34,37,39,41,42,45-47 and 55-60* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *NONE* is/are allowed.

6)☒ Claim(s) *32,34,37,39,41,42,45-47 and 55-60* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendment received on 12/27/2005 wherein claims 32, 55-56, 57 have been amended, claim 44 has been canceled, and new claims 58-60 have been added.

Applicant's amendment to claim 55 by inserting new limitation "wherein the antiseptic composition is packaged in a sterile, non-pyrogenic form" overcomes the rejection of claims 34, 41, 42, and 55 under 35 U.S.C. 102(b) as being anticipated by Fahim (WO 00/13656, PTO-892 of record).

Applicant's amendment to claim 55 by inserting new limitations "wherein the antiseptic composition is packaged in a sterile, non-pyrogenic form" overcomes the rejection of Claims 55, 34, 41, 42 under 35 U.S.C. 102(b) as being anticipated by Kurginski (GB 1 279 148, PTO-892 of record).

Applicant's arguments are not persuasive, and the rejection of claims 32, 39, 44, 45, and 56-57 under 35 U.S.C. 103(a) as being unpatentable over Fahim (WO 00/13656), in view of Wilder (US 6,500,861, PTO-892) is MAINTAINED. See under response to arguments.

Applicant's arguments are not persuasive, and the rejection of claim 46 under 35 U.S.C. 103(a) as being unpatentable over Fahim (WO 00/13656, PTO-892), in view of Wilder (US 6,500,861, PTO-892), and further in view Remington's Pharmaceutical Sciences is MAINTAINED. See under response to arguments.

Applicant's arguments are not persuasive, and the rejection of Claim 47 under 35 U.S.C. 103(a) as being unpatentable over Fahim (WO 00/13656), in view of Wider (US

6,500,861 B1), and further in view of Root et al. (Antimicrobial Agents and Chemotherapy. Nov. 1988, pages 1627-1631, PTO-892) is MAINTAINED. See under response to arguments.

Applicant's arguments are not persuasive, and the rejection of Claims 32, 37, 44, 45, 56-57 under 35 U.S.C. 103(a) as being unpatentable over Kurginski (GB 1 279 148, PTO-892 of record), in view of Fahim (WO 00/13656), and in view of Wilder (US 6,500,861 B1) is MAINTAINED. See under response to arguments.

Claims 32, 34, 37, 39, 41-42, 45-47, and 55-60 are pending, and examined herein.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 57, and 59 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "sufficient" in claim 57 is a relative term which renders the claim indefinite. The term "sufficient" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The term "sufficient"

is vague as it is not clear as to the concentration of EDTA salt in the composition needed to have antimicrobial activity.

35 USC § 103 Rejection

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 32, 34, 39, 41, 42, 45, and 55-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fahim (WO 00/13656) above, in view of Wilder (US 6,500,861, PTO-892).

Fahim discloses antimicrobial compositions comprising about 0.025 to about 8.0 % by weight EDTA or its sodium salts such as tetra sodium EDTA, and the composition has a pH from about 5.0 to about 11.0. See page 10, lines 10-25; and page 11, lines 6-10. It is also taught that the viscosity of the composition can be adjusted by adding sodium chloride. See page lines 15-16. The antimicrobial properties of the compositions were also reported. It is further taught that by increasing the EDTA-Na4 concentration from 2 to 3.0 % by weight provided a substantial increase in bacteria reduction. See page 23, Table 8, prototype 10, wherein the composition comprises 3 % by weight of tetra sodium EDTA, NaCl, water and a pH of 9.5. The antimicrobial compositions comprising tetra-sodium EDTA taught by Fahim are used for topical application such as for cleaning skin. See page 41, claims 35-37.

Fahim does not expressly teach that the composition is packaged in a sterile, pyrogen free form.

Wider teaches antimicrobial compositions for eliminating infections from various surfaces and materials, including the surface of the body. It is also taught that the antimicrobial compositions can be administered as a liquid either orally or through a suitable delivery system, such as a catheter. See column 1, lines 8-20; column 2, lines 30-34; and column 4, lines 10-14. It is further taught that the antimicrobial compositions are packaged in a sterile and pyrogen free form, and can be introduced into the abdominal cavity through a catheter. See column 6, lines 9-10; column 7, lines 51-55.

It would have been obvious to a person of ordinary skill in the art to employ the antimicrobial composition of Fahim in a sterile pyrogen free condition because Wider teaches antimicrobial compositions as packaged in a sterile and pyrogen free form.

One of ordinary skill in the art at the time of invention would have been motivated to employ the claimed antiseptic compositions in a sterile pyrogen free form as conventional with antimicrobial compositions with the expectation of using the composition in catheters.

While the references does not explicitly state that "composition has an osmolarity of from 240-500 mOsM/Kg", as in claim 55, since Fahim discloses the same sodium salts of EDTA as that recited in the instant invention, the composition should possess claimed properties. A compound and its properties are inseparable (*IN re Papesch*, 315 F.2d 381, 137 USPQ 43 (CCPA 1963), thus, since Fahim discloses the same

tetrasodium EDTA as that recited in the instant invention, the composition should possess claimed properties.

While the references does not explicitly state that "the EDTA salt provides at least 50 % of a total antimicrobial activity of the composition" as in claims 58-60, since Fahim discloses the same sodium salts of EDTA as that recited in the instant invention, the composition should possess claimed properties. A compound and its properties are inseparable (*IN re Papesch*, 315 F.2d 381, 137 USPQ 43 (CCPA 1963), thus, since Fahim discloses the same salts of EDTA as that recited in the instant invention, the composition should possess claimed properties.

In claim 56, the intended use of a product or composition "wherein the lock flush composition is biocompatible for use in in-dwelling access catheters, urinary catheters, nasal tubes and throat tubes", do not further limit the claim because the recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Claim 47 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fahim (WO 00/13656), in view of Wider (US 6,500,861 B1), as applied to Claims 32, 34, 39, 41, 42, 45, and 55-60 above, and further in view of Root et al. (Antimicrobial Agents and Chemotherapy. Nov. 1988, pages 1627-1631, PTO-892).

Fahim, and Wider are as discussed above.

Fahim does not specifically teach the antimicrobial composition in a single-dosage vial.

Root et al. teaches a method for disinfecting a catheter by contacting (flushing) with an antimicrobial composition of aqueous EDTA solution having a concentration of 20 mg/ml. The EDTA used by Root et al. is in the form of the disodium salt. Root also teaches that the EDTA is used as a topical antiseptic in gram-negative infections. See page 1627, paragraphs 3, and 6. Root further teaches a sterile polystyrene test tubes (vials) containing the antimicrobial composition of disodium EDTA at a concentration of 20 mg/ml (2 %). See page 1628, lines 18-21.

It would have been obvious to a person of ordinary skill in the art to employ the antimicrobial composition of Fahim in a sterile condition in a single-dosage vial from the teachings of Root et al.

Claim 46 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fahim (WO 00/13656, PTO-892), in view of Wilder (US 6,500,861, PTO-892), as applied to 32, 34, 39, 41, 42, 45, and 55-60 above, and further in view Remington's Pharmaceutical Sciences.

Fahim fails to recite the employment of the composition in a prefilled syringe.

Remington's Pharmaceutical Sciences teaches sterile, pyrogen free solutions of sodium chloride as ideal for injection. It also discloses that hypodermic syringes are used for injection of liquids. See page 1837. Remington also warns against injection of

solutions containing pyrogens (See page 835, column 2, paragraph 1), and to maintain conventional sterile methodology for injected medicaments.

Possessing this teaching by Remington Pharmaceutical Sciences the skilled artisan would have been motivated to provide a syringe filled with an EDTA solution with the expectation of using such sterile, pyrogen free solution for injection.

Claims 32, 34, 37, 41, 42, 45, 55-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kurginski (GB 1 279 148, PTO-892 of record), in view of Fahim (WO 00/13656), and Wilder (US 6,500,861 B1).

Kurginski teaches a composition comprising alkali metal salts or partial salts of ethylenediaminetetraacetic acid (EDTA) in an amount of 0.25 to 15 parts by weight i.e 0.25-15 %, a loweralkanol of 1 to 4 carbon atoms in the amount of 1 to 5 parts i.e less than 10 %, (such as methanol, ethanol etc), an alkanolamine in an amount of 0.8 to 6 parts, a mixture of two or more different loweralkyl ether alcohols in an amount of 1 to 5 parts, and the rest is water in an amount to complete said composition, for cleaning soils that accumulate in toilets and sanitary facilities due to bacterial and fungal growth by applying to the surface said composition. See page 1, lines 12-15, lines 61-64. The PH of the composition is from 7 to 12. See page 2, lines 17-22, lines 48-52, lines 59-60; page 4, claims 1, 4, 5. See EXAMPLE 1, page 4, wherein tetrasodium salt of ethylenediaminetetraacetic acid is used, and the pH is 10.2.

Kurginski does not expressly teach that the composition is packaged in a sterile, pyrogen free form.

Fahim discloses antimicrobial compositions comprising about 0.025 to about 8.0 % by weight of a salt of EDTA such as tetra sodium EDTA, and the composition has a pH from about 5.0 to about 11.0. See page 10, lines 10-25; and page 11, lines 6-10.

Wilder teaches antimicrobial compositions for eliminating infections from various surfaces and materials including the surface of the body. .It is also taught that the antimicrobial compositions can be administered as a liquid either orally or through a suitable delivery system, such as a catheter. See column 1, lines 8-20; column 2, lines 30-34; and column 4, lines 10-14. It is further taught that the antimicrobial compositions are packaged in a sterile and pyrogen free form, and can be introduced into the abdominal cavity through a catheter. See column 6, lines 9-10; column 7, lines 51-55.

It would have been obvious to a person of ordinary skill in the art to employ the compositions comprising sodium salts of EDTA as antimicrobial composition, as Fahim teaches that the compositions comprising tetra-sodium EDTA can be used as antimicrobial compositions.

It would have been obvious to a person of ordinary skill in the art to employ the antimicrobial composition of Fahim in a sterile pyrogen free condition because Wider teaches antimicrobial compositions as packaged in a sterile and pyrogen free form.

Thus from the teachings of Fahim, and Wilder, one of ordinary skill in the art at the time of invention would have been motivated to employ the claimed antiseptic compositions in a sterile pyrogen free form as conventional with antimicrobial compositions with the expectation of using the composition in catheters.

While the references does not explicitly state that "the EDTA salt provides at least 50 % of a total antimicrobial activity of the composition" as in claims 58-60 is the property of the composition, since Kurginski discloses the same sodium salt of EDTA as that recited in the instant invention, the composition should possess claimed properties. A compound and its properties are inseparable (*IN re Papesch*, 315 F.2d 381, 137 USPQ 43 (CCPA 1963), thus, since Kurginski discloses the same sodium salt of EDTA as that recited in the instant invention, the composition should possess claimed properties.

Response to Arguments

Claim Rejection- 35 U.S.C. 103(a):

Rejection under 35 U.S.C. 103(a) as being unpatentable over Fahim (WO 00/13656) above, in view of Wilder (US 6,500,861, PTO-892), rejection of record:

Applicants argument that "One skilled in the art would not be motivated by the teaching of a sterile, pyrogen-free dialysis fluid to modify a handwash. A handwash is not intended for potential contact with a patient's bloodstream or otherwise be possibly introduced into a patient's body. This argument is not persuasive because Fahim teaches an antimicrobial composition comprising EDTA salts in a solution which reads on instant composition, and Wilder teaches that antimicrobial compositions are packaged in a sterile pyrogen free form. Thus, from the teachings of Wilder, one of ordinary skill in the art would have been motivated to employ a conventional sterile, pyrogen free packaging for the antimicrobial composition of Fahim with the expectation

of using the composition in catherates. Note that claim 41 recites that the composition is formulated for topical application to surfaces and objects, which includes application to skin.

Applicant's arguments that "At best, the Office could take the position that it would be obvious to try the combination of prior art documents in the manner hypothesized in the Office Action have been considered but not found persuasive. In contract to applicant's assertions of the rejection is based upon an "obvious to try" standard, it is well known that the ultimate conclusion of law that claimed subject matter as a whole would have been obvious under 35 USC 103 may at times properly be drawn from an inference of fact arising from prior art teachings which could be considered as inference that it would be "obvious to try" that which is claimed.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period, will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shobha Kantamneni whose telephone number is 571-272-2930. The examiner can normally be reached on Monday-Friday, 8am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Shobha Kantamneni
Patent Examiner
Art Unit 1617.

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER